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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
EASTERN DIVISION

Jules Berck

Plaintiff,

vs.

Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals North America, Inc.;Takeda Pharmaceutical Company Limited; and Eli Lilly and Company

Defendants.

Case No. EDCV11-1226 VAP (OPx)

BY FAX

COMPLAINT AND DEMAND FOR JURY TRIAL

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COMPLAINT

Plaintiff Jules Joseph Berck (alternatively referred to as "Plaintiff"), residing in Winchester within the State of California, by and through the undersigned attorneys, hereby brings this cause of action against Defendants Takeda Pharmaceuticals America, Inc. ("Takeda America"), Takeda Pharmaceuticals North America, Inc. ("Takeda North America") and Takeda Pharmaceutical Company Limited ("Takeda Limited") (collectively "Takeda" or "Defendants") and Eli Lilly and Company ("Lilly" or

collectively with Takeda as "Defendants") and as for his/her Complaint alleges, upon information and belief and based on the investigation to date of counsel, as follows:

INTRODUCTION

1. This is a personal injury action brought for injuries caused to Plaintiff as a result of ingesting Defendants' defective drug Actos (pioglitazone), a prescription medication used to improve blood sugar (glucose) control in adults with type II diabetes.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are all incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

3. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiffs' claims occurred, in part, in the Central District of California.

PLAINTIFF

5. Plaintiff, Jules Berck, is a natural person and a resident of 34629 Foxberry Road, Winchester in the State of California and used the prescription Actos as prescribed and directed by his/her physician(s).

6. Plaintiff was injured as a result of his use of Actos, and therefore seeks damages, ascertainable economic losses, attorneys' fees, reimbursement of cost of obtaining Actos, reimbursement for all past, present, and future health and medical care costs related to Actos.

DEFENDANTS

7. Takeda America is a Delaware Corporation, which has its principal place of business at One Takeda Parkway Deerfield, IL 60015.

8. Takeda America is a wholly owned subsidiary of Takeda North America.

9. Takeda America has transacted and conducted business within the State of California.

10. Takeda America has derived substantial revenue from goods and products used in the State of California.

11. Takeda America expected or should have expected their acts to have consequences within the State of California, and derived substantial revenue from interstate commerce.

12. Takeda North America is a Delaware corporation, which has its principal place of business at One Takeda Parkway Deerfield, IL 60015.

13. Takeda North America is a wholly owned subsidiary of Takeda Limited.

14. Takeda North America has transacted and conducted business within the State of California.

15. Takeda North America has derived substantial revenue from goods and products used in the State of California.

16. Takeda North America expected or should have expected their acts to have consequences within the State of California, and derived substantial revenue from interstate commerce.

17. Takeda Limited is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, 540-8645, Japan.

18. Takeda Limited is the parent company of Takeda North America, and Takeda America is a wholly owned subsidiary of Takeda North America.

19. Takeda Limited has transacted and conducted business within the State of California.

20. Takeda Limited has derived substantial revenue from goods and products

used in the State of California.

21. Takeda Limited expected or should have expected their acts to have consequences within the State of California, and derived substantial revenue from interstate commerce.

22. Lilly is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

23. Lilly has transacted and conducted business within the State of California.

24. Lilly has derived substantial revenue from goods and products used in the State of California.

25. Lilly expected or should have expected their acts to have consequences within the State of California, and derived substantial revenue from interstate commerce.

SUMMARY OF THE CASE

26. From on or about June 2005 until on or about December 2008, Plaintiff Jules Berck took Actos manufactured and distributed by Defendants for treatment of type II diabetes.

27. As a result of the defective nature of Actos, persons who were prescribed and who subsequently ingested this product, including Plaintiff, have suffered and may continue to suffer from bladder cancer.

28. Defendants concealed and continue to conceal their knowledge of Actos' unreasonably dangerous risks from Plaintiff, his physicians, other consumers, and the medical community. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the risk of bladder cancer associated with more than twelve (12) months of Actos ingestion.

29. As a result of Defendants' actions and inaction, Plaintiff was injured due to his ingestion of Actos, which caused and will continue to cause Plaintiff's injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

FACTUAL ALLEGATIONS

30. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted and sold Actos, for the treatment of type two diabetes mellitus.

31. According to the American Diabetes Association, type II diabetes is the most common form of diabetes. Type II diabetes develops when the body does not produce enough insulin or doesn't efficiently use the insulin that it does produce. Type I diabetes occurs when the body does not produce any insulin at all. Insulin is necessary for the body to be able to use glucose for energy.

32. Actos was jointly launched by Takeda North America and Lilly in 1999.

33. Actos was approved by the Food and Drug Administration ("FDA") in July of 1999 to treat type II diabetes.

34. Actos is in a class of insulin-sensitizing diabetes agents known as thiazolidinediones ("TZD"s).

35. On April 20, 2006, Takeda Limited announced the conclusion of its collaboration in the United States between Takeda North America and Lilly to promote and market Actos.

36. Takeda Limited described this partnership as "a great success" and "mutually beneficial to both companies."

37. Actos exerts its antihyperglycemic effect only in the presence of endogenous insulin. Therefore, Actos is only used to treat type II diabetes and should not be used to treat type I diabetes.

38. Actos is sold as a single ingredient product under the brand name Actos.

39. Actos is also sold in combination with metformin (Actoplus Met, Actoplus Met XR) and in combination with glimepiride (Duetact).

40. As a result of the defective nature of Actos, persons who were prescribed and ingested Actos for more than twelve (12) months, including Plaintiff, were at increased risk for developing bladder cancer, have suffered and may continue to suffer

from bladder cancer.

41. As a result of the defective nature of Actos, persons who were prescribed and ingested Actos for more than twelve (12) months, including Plaintiff, developed bladder cancer, have suffered and may continue to suffer from bladder cancer

42. Defendants concealed and continue to conceal their knowledge that Actos can cause bladder cancer from Plaintiff, other consumers, and the medical community.

43. Specifically, Defendants have yet to adequately inform consumers and the prescribing medical community about the risks of bladder cancer with use of Actos for more than twelve (12) months.

44. As a result of Defendants' actions and inactions, Plaintiff was injured due to his/her ingestion of Actos, which caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

45. Prior to Actos being approved by the FDA, a two-year carcinogenicity study was conducted on male and female rats. Drug-induced tumors were observed in male rats receiving doses of Actos that produced blood drug levels equivalent to those resulting from a clinical dose.

46. In 2005, the results of the PROactive (**PRO**spective Pioglit**A**zone **C**linical **T**rial **I**n Macro**V**ascular **E**vents) three-year study were published. PROactive prospectively looked at the impact in total mortality and macrovascular morbidity using Actos. Dormandy J.A., et al. *Secondary Prevention of Macrovascular Events in Patients with Type 2 Diabetes in the PROactive Study (PROspective PioglitAzone Clinical Trial In MacroVascular Events): a Randomised Controlled Trial*, Lancet, 266:1279-1289 (2005).

47. The PROactive study was looking at cardiovascular events and outcomes.

48. During the course of monitoring the study, the researchers and Defendants became aware that there was a statistically significant demonstrated higher percentage of bladder cancer cases in patients receiving Actos versus comparators.

49. Neither during the study, nor in the actual final Dormandy paper, did the researchers or the Defendants publish these statistically significant increases of bladder cancer.

50. This information was not included in the published Dormandy paper.

51. Defendants willfully, wantonly and with malice withheld the knowledge of increased risk of cancer in users of Actos to prevent any chances of its products registration being delayed or rejected by FDA

52. A three-year liver safety study was also performed, and according to the FDA, that study also demonstrated a higher percentage of bladder cancer cases in patients receiving Actos versus comparators.

53. On September 17, 2010, the FDA issued a Safety Announcement stating it was undertaking a review of the data from an ongoing, ten-year epidemiological study being conducted by Kaiser Permanente to evaluate the association between Actos and bladder cancer. The planned five-year interim analysis demonstrated that the risk of bladder cancer increases with increasing dose and duration of Actos use, reaching statistical significance after 24 months.

54. In a shocking spin on words, despite FDA finding that Actos is linked to a statistically significant increase in the risk for developing bladder cancer, Robert Spanheimer, Vice President of Medical and Scientific Affairs for Takeda, claimed to Reuters that the Kaiser Permanente study has not shown a risk to patients of bladder cancer or other cancers from Actos.

55. In early 2011, the American Diabetes Association published *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting,* Piccinni, et al. Diabetes Care, 34:1369-1371 (June 2011), published ahead of print April 22, 2011. This study looked at adverse events reports made to FDA between 2004 and 2009. The conclusion of that study was that "[i]n agreement with preclinical and clinical studies, AERS analysis is consistent with an association between pioglitazone and bladder cancer. This issue needs constant epidemiologic surveillance

and urgent definition by more specific studies."

56. On June 9, 2011, the European Medicines Agency ("EMA") announced that it had been informed by the French Medicines Agency ("Afssaps") of its decision to suspend the use of pioglitazone-containing medicines (Actos, Competact) in France while awaiting the outcome of the ongoing European review.

57. France's decision was based upon a retrospective cohort study in France using the French National Health Insurance Plan, which demonstrated a statistically significant increase in the risk for bladder cancer in males exposed to Actos for more than a year. The French cohort included 1.5 million patients with diabetes that were followed for 4 years (2006-2009).

58. On June 10, 2011, Reuters published that Germany had joined France in suspending the use of Actos after Germany's Federal Institute for Drugs and Medical Devices ("BfArM") reviewed the results of the French study. BfArM recommended that doctors should not put new patients on pioglitazone.

59. On June 15, 2011, the FDA issued another Safety Announcement stating that "use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer." The FDA ordered information about this risk to be added to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines.

60. The FDA reported that the risk of bladder cancer increased with increasing dose and duration of pioglitazone use. When compared to persons never exposed to pioglitazone, exposed to pioglitazone therapy for longer than 12 months was associated with a 40% increase in risk. Based on this data, the FDA calculated that therapy with Actos for longer than 12 months was associated with 27.5 excess cases of bladder cancer per 100,000 person-years follow-up, compared to those who never used pioglitazone.

61. On July 12, 2011, Takeda Limited issued a recall on Actos in France.

62. Following the recall in France, Takeda Limited refused to issue a recall of

Actos in the United States thereby continuing to subject American Citizens to the significant risk of developing bladder cancer while ensuring the users in France and Germany were no long subject to this risk.

63. As the manufacturers of Actos, Defendants knew or should have known that Actos use for longer than twelve (12) months was associated with bladder cancer.

64. With the knowledge of the true relationship between long-term use of Actos and developing bladder cancer, rather than take steps to pull the drug off the market, Defendants promoted Actos as a safe and effective treatment for type II diabetes.

65. Piccinni, et al. analyzed the association between antidiabetic drugs and bladder cancer by reviewing reports from the FDA Adverse Event Reporting System ("AERS") between 2004 and 2009. The association was analyzed by the case/noncase methodology. There were 31 recorded reports of bladder cancer in patients using pioglitazone. Piccinni's results indicated that the reporting odds ratio for pioglitazone was indicative of a "definite risk." *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting,* Piccini, et al. Diabetes Care, 34:1369-1371 (June 2011), published ahead of print April 22, 2011.

66. Despite its knowledge of this dangerous side effect that can result from Actos use, Defendants refused to warn patients, physicians and the medical community about the risk of bladder cancer.

67. Actos is one of Defendants' top selling drugs. Upon information and belief, in the last year, the medication had global sales of $4.8 billion and accounted for approximately 27% of Takeda's revenue.

68. In 2008, with the knowledge of the risk associated with developing bladder cancer while using Actos long term, Takeda Limited achieved its marketing goal by making Actos the tenth best-selling medication in the United States all while placing American Citizens at risk of developing bladder cancer.

69. Consumers, including Plaintiff, who have used Actos for treatment of type II diabetes, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with long-term Actos therapy.

70. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with long-term Actos use.

71. As a result of Defendants' actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

72. Plaintiff was prescribed and began taking Actos upon direction of his physicians. Plaintiff subsequently developed bladder cancer.

73. As a direct result of being prescribed Actos for many years Plaintiff has been permanently and severely injured, having suffered serious consequences from long-term Actos use.

74. Plaintiff requires and will in the future require ongoing medical care and treatment.

75. Plaintiff, as a direct and proximate result of long-term Actos use, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living related expenses due to his new lifestyle.

76. Plaintiff would not have used Actos had Defendants properly disclosed the risks associated with its long-term use.

FEDERAL REQUIREMENTS

77. Defendants had an obligation to comply with the law in the manufacture, design, and sale of Actos.

78. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.*

79. With respect to the prescription drug Actos, the Defendants, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for ACTOS and such deviations are not plainly stated on their labels.

c. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because, among other things, it's labeling is false or misleading.

d. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352

because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. The prescription drug Actos does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. The prescription drug Actos is misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Actos cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.

k. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Actos.

l. The Defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug Actos are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.

m. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

n. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

o. The Defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug Actos and other drugs in the same pharmacologically active and chemically related class.

p. The Defendants violated 21 CFR § 201.57 because the possibility that a patient could develop Cardiac Arrhythmia after significantly more severe than the other reactions listed in the adverse reactions, and yet the Defendants failed to list the development of Cardiac Arrhythmia

before the other adverse reactions on the labeling of the prescription drug Actos.

q. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

r. The prescription drug Actos violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

s. The prescription drug Actos violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

t. The prescription drug Actos violates 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

u. The prescription drug Actos violates 21 CFR § 211.165 in that the prescription drug ACTOS fails to meet established standards or specifications and any other relevant quality control criteria.

v. The prescription drug Actos violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug Actos were not followed.

w. The prescription drug Actos violates 21 CFR § 310.303 in that the prescription drug Actos is not safe and effective for its intended use.

x. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

y. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug Actos as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.

z. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug Actos, and evaluating the cause of the adverse event.

aa. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

bb. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

cc. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report followup."

dd. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug Actos or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or

epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ee. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. The Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

80. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendants liable under California law.

FIRST CAUSE OF ACTION

FRAUD

81. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

82. Defendants disseminated the false information, as referenced above, to physicians and, indirectly, to their patients, knowing the information to be false or in

conscious disregard of whether it was false or not false, with the intention to deceive physicians and, indirectly, their patients, and to induce physicians to prescribe Actos.

83. Specifically, Defendants made express representations of safety associated with long-term use of Actos while it knowingly concealed a known statistically significant risk of developing bladder cancer while taking Actos.

84. Defendants knowingly concealed research data that linked Actos to a high rate of bladder cancer yet marketed the drug as safe.

85. Defendants knowingly made representations of safety in advertising materials, its sales force marketing presentations and in its labeling and packaging while withholding actual knowledge from peer reviewed scientific studies it was either sponsoring, funding or participating in that established that the product was unsafe and put patients at risk for developing bladder cancer.

86. As a foreseeable and proximate result of this dissemination of knowingly and/or recklessly false information, as referenced above, Plaintiff Jules Berck suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in foreseeable and reasonable reliance upon this false information disseminated by Defendants, and believing the information to be true, prescribed for Plaintiff the use of Actos for a period of more than twelve (12) months. Plaintiff ingested, per those prescriptions, Actos, which directly and proximately caused his injury.

SECOND CAUSE OF ACTION

FRAUD BY CONCEALMENT

87. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

88. Defendants, with the intention of deceiving physicians and their patients, and to induce physicians to prescribe, and their patients to ingest, Actos for prolonged periods of time, informed physicians, through the Actos label and dissemination of

materials relating to Actos, that, rather than acknowledging that Defendants' product causes bladder cancer, Defendants describe Actos as being safe.

89. Plaintiff's physicians, in reasonable reliance upon the information thus disseminated by Defendants, and without knowledge of the undisclosed and knowingly concealed facts, determined erroneously that the benefits of prolonged Actos therapy outweighed the risks for their patient, Jules Berck, and prescribed a course of Actos therapy for a time exceeding twelve (12) months.

90. As a direct, proximate and foreseeable result of Defendant's knowing and fraudulent concealment of material facts, as described above, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in reasonable reliance upon the information disseminated by Defendants, and in ignorance of the facts concealed from them in the materials disseminated, prescribed for Plaintiff the use of Actos, which Plaintiff used per those prescriptions, leading to his injuries.

THIRD CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

91. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

92. Defendants owed a duty in all of its undertakings, including the dissemination of information concerning Actos, to exercise reasonable care to ensure that it did not in those undertakings create unreasonable risks of personal injury to others.

93. Defendants disseminated to physicians, through published labels and otherwise, information concerning the properties and effects of Actos with the intention that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients.

94. Defendants, as prescription drug manufacturers and/or distributors, knew

or reasonably should have realized that physicians, in weighing the potential benefits and potential risks of using Actos, would rely upon information disseminated to them by the manufacturer of the name brand product, and that many patients, in accordance with those prescriptions, would be likely to ingest Actos as properly dispensed by their pharmacies.

95. Defendants, as prescription drug manufacturers and/or distributors, knew or reasonably should have realized that patients receiving prescriptions for Actos, written by physicians in reliance upon information disseminated by Defendants as the manufacturer/distributor of Actos, would be placed in peril of grievous personal injury if the information disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

96. Defendants failed to exercise reasonable care to ensure that the information it disseminated to physicians concerning the properties and effects of Actos was accurate and not misleading, and, as a result, disseminated information to physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff.

97. As a direct, proximate and foreseeable result of Defendants' negligence, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in reasonable reliance upon the negligently inaccurate, misleading, and otherwise false information disseminated by Defendants, and believing the information to be true, prescribed for Plaintiff the use of Actos for a prolonged and unwarranted period of time, exceeding twelve (12) months. Plaintiff ingested Actos as prescribed and instructed by his physician, leading to his injuries.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY

98. Plaintiff incorporates by reference each preceding paragraph as though set

forth fully at length herein

99. The dangerous propensities of Actos were known to Defendants, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

100. The Actos products as distributed by Defendants were defective and unreasonably dangerous prescription drug products, as Defendant failed to provide appropriate and adequate warnings and instructions to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses; in particular – the common, foreseeable and intended use of Actos therapy as long-term maintenance for type II diabetes.

101. At all times relevant to this action, Defendants manufactured, supplied, and/or sold Actos in a defective and dangerous condition, as described above, to physicians, including Plaintiff's physician.

102. As a direct, foreseeable and proximate result of Defendants' defective Actos product, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, as referenced above, when his physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) Defendants provided to physicians for their respective products, prescribed for Plaintiff the use of Actos for s prolonged and unwarranted period of time exceeding twelve (12) months).

FIFTH CAUSE OF ACTION

NEGLIGENCE

103. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

104. As a manufacturer of a prescription pharmaceutical drug product,

Defendants owed a duty toward foreseeable users of Actos, including Plaintiff, to exercise reasonable care to ensure that Actos products, as manufactured and/or distributed, were reasonably safe for their ordinary and intended uses and, specifically, to ensure through adequate testing, labeling, and otherwise, that physicians (and their patients) were adequately informed as to the potential effects and inherent risks of using Actos in an ordinary and foreseeable manner.

105. Defendants breached the duties they owed to exercise reasonable care for the safety of users of their products, including Plaintiff, by failing to exercise reasonable care in testing their products to identify all inherent risks and associated effects when used in an ordinary and foreseeable manner.

106. Defendants also breached the duties they owed to exercise reasonable care for the safety of users of their products, including Plaintiff, by negligently failing to disseminate, in a manner reasonably calculated to be seen and read by physicians (or their patients), information concerning their respective products' effects, which was accurate, not misleading, and otherwise adequate to enable physicians (or their patients) to make informed choices concerning the reasonably safe use of their products.

107. As a direct, foreseeable and proximate result of Defendants' breaches of their duties to exercise reasonable care for the safety of users of their respective products, by negligently failing to adequately test Actos and negligently failing to provide adequate warnings and instructions for same, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) Defendants provided to physicians.

SIXTH CAUSE OF ACTION

NEGLIGENCE *PER SE*

108. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

109. As part of their duty to exercise reasonable care for the safety of persons, including Plaintiff, who would be expected to use their products, Defendants were obliged to follow public laws and regulations enacted and promulgated to protect the safety of such persons, including 21 U.S.C. §§ 331(a) and 352, and California Health and Safety Codes §§ 111330 -111510, which make it unlawful to misbrand prescription drug products.

110. The package inserts (and other labeling, if any) for each of the Actos products failed to conform to the requirements of 21 U.S.C. §352, including subsections (a), (c), and (f), or the requirements of 21 C.F.R. § 201.100(c)(1), and, therefore, violated 21 U.S.C. § 331(a), and also violated California Health and Safety Codes §§ 111330-111510, as the package inserts and/or other labeling failed to contain, *inter alia,* information, including warnings and instructions for use, adequate to enable the use of Actos in an ordinary, foreseeable, and intended manner that was reasonably safe, taking into account the potential benefits and potential risks entailed in such use, or to bear "information for its use, including . . . any relevant hazards, contraindications, side effects, and precautions" that were adequate to enable doctors to "use the drug safely and for the purposes for which it is intended;" and, in addition, contained false, inaccurate, and/or misleading statements concerning their respective products' side effects.

111. Accordingly, Defendants, in distributing the Actos products labeled in violation of these statutes and associated regulations, were negligent *per se.* That is, negligent as a matter of law.

112. As a direct, foreseeable and proximate result of the negligence per *se* of Defendants, specifically, their violations of the above-referenced statutes and regulations, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in reasonable reliance on Defendants' compliance with these health and safety laws and regulations, prescribed for Plaintiff the use of Actos for a prolonged and unwarranted period of time exceeding

twelve (12) months. Plaintiff ingested Actos as prescribed and instructed by his physician, leading to his injuries.

SEVENTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

113. Plaintiffs incorporate by reference each preceding paragraph as though set forth fully at length herein.

114. The Actos product materially failed to conform to those representations made by Defendants in package inserts, and otherwise, concerning the properties and effects of the Actos products, respectively manufactured and/or distributed and sold by Defendants, and which Plaintiff purchased and ingested in direct or indirect reliance upon these express representations. Such failure by Defendants constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Actos sold to Plaintiff.

115. As a direct, foreseeable and proximate result of Defendants' breaches of express warranties, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in reasonable reliance upon such express warranties, prescribed for Plaintiff the use of Actos for a prolonged and unwarranted period of time exceeding twelve (12) months. Plaintiff purchased and ingested Actos as prescribed and instructed by his physician, leading to his injuries.

EIGHTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

116. Plaintiffs incorporate by reference each preceding paragraph as though set forth fully at length herein.

117. Defendants impliedly warranted their respective Actos products, which

they manufactured and/or distributed and sold, and which Plaintiff purchased and ingested, to be of merchantable quality and fit for the common, ordinary, and intended uses for which the products were sold.

118. Defendants breached their implied warranties of the Actos products sold to Plaintiff because these products were not fit for their common, ordinary, and intended use.

119. As a direct, foreseeable and proximate result of Defendants' breaches of implied warranties, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in reasonable reliance upon the implied warranties, prescribed for Plaintiff the use of Actos for a prolonged and unwarranted period of time exceeding twelve (12) months. Plaintiff purchased and ingested Actos as prescribed and instructed by his physician, leading to his injuries.

NINTH CAUSE OF ACTION

UNFAIR TRADE PRACTICES IN VIOLATION OF CALIFORNIA *BUSINESS AND PROFESSIONS CODE*

120. Plaintiffs incorporate by reference each preceding paragraph as though set forth fully at length herein.

121. Defendants, through the use of false and/or misleading advertising, representations, and statements, as described above, induced Plaintiff (through his physicians, as learned intermediaries between himself and the drug companies) to use and consume the Actos products manufactured and/or distributed and sold by Defendants in violation the California *Business and Professions Code,* Division 7, Part 2, Preservation and Regulation of Competition, which proscribes, among other things:

a. Engaging in unfair trade practices as defined in this statute by making false and misleading written statements that have the capacity, tendency, or effect of deceiving or misleading consumers;

b. Engaging in unfair trade practices as defined in this statute by making

representations that their products had a use or benefit which they did not have, including but not limited to statements concerning the health consequences of the use of drugs;

c. Engaging in unfair trade practices as defined in this statute by failing to state material facts, the omission of which deceive or tend to deceive, including but not limited to, facts relating to the health consequences of the use of these drugs; and

d. Engaging in unfair trade practices as defined in this statute through deception, fraud, misrepresentation, and knowing concealment, suppression, and omission of material facts with the intent that consumers rely upon the same in connection with the use and continued use of the drugs.

122. As a result of the aforesaid statutory violations, Plaintiffs are entitled to relief, as prayed for below.

PUNITIVE DAMAGES

123. Plaintiffs incorporate by reference each preceding paragraph as though set forth fully at length herein.

124. At the expense of and in conscious disregard for the health and safety of those who consequently would develop bladder cancer, Defendants marketed Actos to physicians, as hereinabove described, in a manner calculated to increase sales of the drug and resultant profits to the drug company.

125. As part of promotional efforts intentionally aimed at increasing inappropriately unsafe but profitable prescribing of Actos, Defendants sponsored the performance of knowingly non-scientific investigations, and created and disseminated reports from those investigations, to suggest that Actos is safe, and minimized and/or

failed to state the risks associated with bladder cancer; Defendants chose to develop and disseminate other information, including the Actos product labeling, to fail to state a known link between bladder cancer and Actos use for a period exceeding twelve (12); and otherwise systematically suppressed or downplayed, in the information it disseminated, specific scientific information about the risks and prevalence of side effects associated with Actos.

126. By this conduct, Defendants acted with oppression, fraud, and malice, evincing a willful, wanton, and conscious disregard for the rights, health, and safety of patients, including Plaintiff who would be expected to be induced, by such conduct, to use Actos, leading to grievous, debilitating, and permanent personal injury.

127. Defendants' conduct, as alleged, warrants an exaction of punitive damages assessed (a) in an amount reasonably related to Plaintiffs' actual damages and Defendants' wealth and profits from the willful, wanton, and reckless conduct alleged and proved, and (b) sufficiently large to set an example for others and deter similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, as follows:

a. Awarding actual damages to the Plaintiff incidental to his purchase and use of Actos in an amount to be determined at trial;

b. Awarding treble and/or punitive damages to the Plaintiff;

c. Awarding pre-judgment and post-judgment interest to the Plaintiff;

d. Awarding the costs and the expenses of this litigation to the Plaintiff;

e. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law; and

//

f. Granting all such other relief as the Court deems necessary, just and proper.

DATED: August 1, 2011

NAPOLI BERN RIPKA SHKOLNIK & ASSOCIATES, LLP

By: *Marc I. Willick*
Marc I. Willick
Attorney for Plaintiff

DEMAND FOR JURY TRIAL

The Plaintiff hereby demands a trial by jury on all counts and as to all issues.

DATED: August 1, 2011

NAPOLI BERN RIPKA SHKOLNIK & ASSOCIATES, LLP

By: *Marc I. Willick*
Marc I. Willick
Attorney for Plaintiffs

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself ☐)
JULES BERCK

DEFENDANTS
TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS NORTH AMERICA; TAKEDA PHARMACEUTICALS COMPANY LIMITED; ELI LILLY AND COMPANY

(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)
NAPOLI BERN RIPKA SHKOLINK & ASSOCIATES, LLP
2361 Rosecrans Ave, Suite 450
El Segundo, CA 90245 (310) 536-1040

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.)
☐ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)
☐ 2 U.S. Government Defendant ☑ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only (Place an X in one box for plaintiff and one for defendant.) BY FAX

	PTF	DEF		PTF	DEF
Citizen of This State	☑ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☑ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)
☑ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify): ☐ 6 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: **JURY DEMAND:** ☑ Yes ☐ No (Check 'Yes' only if demanded in complaint.)
CLASS ACTION under F.R.C.P. 23: ☐ Yes ☑ No ☐ **MONEY DEMANDED IN COMPLAINT:** $

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)
Diversity Jx (28 U.S.C. § 1332), Fraud, fraud by concealment, negligent misrepresentation, strict products liability, negligence, negligence per se (21 U.S.C. §301, et seq.;

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES	CONTRACT	TORTS	TORTS	PRISONER	LABOR
		PERSONAL INJURY	PERSONAL PROPERTY	PETITIONS	
☐ 400 State Reapportionment	☐ 110 Insurance	☐ 310 Airplane	☐ 370 Other Fraud	☐ 510 Motions to Vacate Sentence Habeas Corpus	☐ 710 Fair Labor Standards Act
☐ 410 Antitrust	☐ 120 Marine	☐ 315 Airplane Product Liability	☐ 371 Truth in Lending	☐ 530 General	☐ 720 Labor/Mgmt. Relations
☐ 430 Banks and Banking	☐ 130 Miller Act	☐ 320 Assault, Libel & Slander	☐ 380 Other Personal Property Damage	☐ 535 Death Penalty	☐ 730 Labor/Mgmt. Reporting & Disclosure Act
☐ 450 Commerce/ICC Rates/etc.	☐ 140 Negotiable Instrument	☐ 330 Fed. Employers' Liability	☐ 385 Property Damage Product Liability	☐ 540 Mandamus/ Other	☐ 740 Railway Labor Act
☐ 460 Deportation	☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 340 Marine	BANKRUPTCY	☐ 550 Civil Rights	☐ 790 Other Labor Litigation
☐ 470 Racketeer Influenced and Corrupt Organizations	☐ 151 Medicare Act	☐ 345 Marine Product Liability	☐ 422 Appeal 28 USC 158	☐ 555 Prison Condition	☐ 791 Empl. Ret. Inc. Security Act
☐ 480 Consumer Credit	☐ 152 Recovery of Defaulted Student Loan (Excl. Veterans)	☐ 350 Motor Vehicle	☐ 423 Withdrawal 28 USC 157	FORFEITURE / PENALTY	PROPERTY RIGHTS
☐ 490 Cable/Sat TV	☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 355 Motor Vehicle Product Liability	CIVIL RIGHTS	☐ 610 Agriculture	☐ 820 Copyrights
☐ 810 Selective Service	☐ 160 Stockholders' Suits	☐ 360 Other Personal Injury	☐ 441 Voting	☐ 620 Other Food & Drug	☐ 830 Patent
☐ 850 Securities/Commodities/ Exchange	☐ 190 Other Contract	☐ 362 Personal Injury-Med Malpractice	☐ 442 Employment	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 840 Trademark
☐ 875 Customer Challenge 12 USC 3410	☐ 195 Contract Product Liability	☑ 365 Personal Injury-Product Liability	☐ 443 Housing/Acco-mmodations	☐ 630 Liquor Laws	SOCIAL SECURITY
☐ 890 Other Statutory Actions	☐ 196 Franchise	☐ 368 Asbestos Personal Injury Product Liability	☐ 444 Welfare	☐ 640 R.R. & Truck	☐ 861 HIA (1395ff)
☐ 891 Agricultural Act	REAL PROPERTY	IMMIGRATION	☐ 445 American with Disabilities - Employment	☐ 650 Airline Regs	☐ 862 Black Lung (923)
☐ 892 Economic Stabilization Act	☐ 210 Land Condemnation	☐ 462 Naturalization Application	☐ 446 American with Disabilities - Other	☐ 660 Occupational Safety /Health	☐ 863 DIWC/DIWW (405(g))
☐ 893 Environmental Matters	☐ 220 Foreclosure	☐ 463 Habeas Corpus-Alien Detainee	☐ 440 Other Civil Rights	☐ 690 Other	☐ 864 SSID Title XVI
☐ 894 Energy Allocation Act	☐ 230 Rent Lease & Ejectment	☐ 465 Other Immigration Actions			☐ 865 RSI (405(g))
☐ 895 Freedom of Info. Act	☐ 240 Torts to Land				FEDERAL TAX SUITS
☐ 900 Appeal of Fee Determination Under Equal Access to Justice	☐ 245 Tort Product Liability				☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 950 Constitutionality of State Statutes	☐ 290 All Other Real Property				☐ 871 IRS-Third Party 26 USC 7609

1- 21 CFR §§ 201.5 et seq., 210.1 et seq., 211.165 et seq., 310.303, 310.305, 312.32, 314.80), breach of express warranty, breach of implied warranty, unfair trade practices (Cal. Bus. & Prof. Code § 17200 et seq.).

FOR OFFICE USE ONLY: Case Number: EDCV11-1226

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? ☑ No ☐ Yes
If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? ☑ No ☐ Yes
If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:
(Check all boxes that apply) ☐ A. Arise from the same or closely related transactions, happenings, or events; or
☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.
☐ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Riverside	

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.
☐ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
	Indianapolis, IN Deerfield, IL Osaka, Japan

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.
Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Riverside, CA	

*** Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties**
Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): Mar Willick **Date** August 1, 2011

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))

COPY

Name & Address:
Marc I. Willick (State Bar No. 175379)
Napoli Bern Ripka Shkolnik & Associates, LLP
2361 Rosecrans Ave, Suite 450
El Segundo, CA 90245
Telephone: (310) 536-1040

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Jules Berck PLAINTIFF(S) v. Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals North America; Inc. Takeda. Pharmaceuticals Company Limited; Eli Lilly and Co. DEFENDANT(S).	CASE NUMBER VAP (OPx) EDCV11-1226 SUMMONS

TO: DEFENDANT(S): Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals North America; Takeda Pharmaceuticals Company Limited; Eli Lilly and Company

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it), you must serve on the plaintiff an answer to the attached ☑ complaint ☐ _____ amended complaint ☐ counterclaim ☐ cross-claim or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff's attorney, Marc Willick (Napoli Bern Ripka Shkolnik & Assoc. LLP), whose address is 2361 Rosecrans Ave, Suite 450, El Segundo, CA 90245. If you fail to do so, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

Clerk, U.S. District Court

Dated: AUG - 2 2011

By: CHRISTOPHER POWER
Deputy Clerk

(Seal of the Court)

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[Use 60 days if the defendant is the United States or a United States agency, or is an officer or employee of the United States. Allowed 60 days by Rule 12(a)(3)].

DOCKETED ON CM
AUG 4 2011
BY 202

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge Virginia A. Phillips and the assigned discovery Magistrate Judge is Oswald Parada.

The case number on all documents filed with the Court should read as follows:

EDCV11- 1226 VAP (OPx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

==========

NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

[ ] **Western Division**
312 N. Spring St., Rm. G-8
Los Angeles, CA 90012

[ ] **Southern Division**
411 West Fourth St., Rm. 1-053
Santa Ana, CA 92701-4516

[X] **Eastern Division**
3470 Twelfth St., Rm. 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.